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REMARKS

Claims 1-6, 10-16, and 20 are in this application. Claims 7-9 and 17-19 have been canceled.

NEW MATTER

The Examiner objects to the amendment filed 27 February 2007 on the ground that incorporating two example U.S. patents by reference into the background art section of the specification has introduced new matter. These two patents have been incorporated in order to emphasize their prior art teaching reflecting the state of the skill of those having skill in the relevant art.

However, in order to place this application in better form for allowance or an appeal, applicants' attorney has canceled the incorporation language.

NON STATUTORY

Claims 1-6, 10 - 16 and 20 have been rejected under 35 U.S.C. 101.

This rejection is respectfully traversed on the ground that the specification and claims indeed do describe a method and a program product that produce a result that has substantial and credible utility as required by MPEP 2107 II and that the claims are limited to a narrow application in a computer related art.

The Examiner relies on the "New Interim Guidelines" to interpret the requirements of the Federal Courts under the current law to require claiming "output to a user". Applicant believes that the Examiner is mistaken and is applying an interpretation of the

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definition of the word tangible that is narrower than appropriate under the 1) current law and is narrower than required under the 2) "New Guidelines".

1) The introduction to the "New Guidelines" states:

These Examination Guidelines ("Guidelines") are based on the USPTO's current understanding of the law and are believed to be fully consistent with binding precedent of the Supreme Court, the Federal Circuit and the Federal Circuit's predecessor courts. **These Guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law.**

The Examiner has followed the "Guidelines" which appear to require separate interpretations of the words useful, concrete and tangible.

Applicants' attorney has found no basis in any of the Federal Circuit opinions using these words that imply that these terms are to have separate meanings. They always are used together as synonyms for the concepts of being useful and non-abstract. If applicants' attorney has overlooked a **court's** requirement that these terms are part of a three pronged test, a citation to such an opinion will be helpful to applicants in deciding whether to appeal or request continued examination.

2) Even under the "Guidelines, the Examiners interpretation of the word tangible is unnecessarily narrow.

The "Guidelines" at page 13 recite

"Accordingly, a complete definition of the scope of 35 U.S.C. § 101, reflecting Congressional intent, is that any new and useful process, machine, manufacture or composition of matter under the sun that is made by man is the proper subject matter of a patent. The subject matter courts have found to be outside of, or exceptions to, the four statutory categories of invention is limited

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to abstract ideas, laws of nature and natural phenomena. While this is easily stated, determining whether an applicant is seeking to patent an abstract idea, a law of nature or a natural phenomenon has proven to be challenging.

Beginning at page 21 the "Guidelines" recite:

"TANGIBLE RESULT"

The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a § 101 judicial exception, in that the process claim must set forth a practical application of that § 101 judicial exception to produce a real-world result. Benson, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because had "no substantial practical application."). "[A]n application of a law of nature or mathematical formula to a ... process may well be deserving of patent protection." Diehr, 450 U.S. at 187, 209 USPQ at 8 (emphasis added); see also Coming, 56 U.S. (15 How.) at 268, 14 L.Ed. 683 ("It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted ..."). In other words, the opposite meaning of "tangible" is "abstract."

The bare conversion of any binary data as in Gottschalk V. Benson or the bubble sort of any data as in "Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759 ("steps of 'locating' a medial axis, and 'creating' a bubble hierarchy ... describe nothing more than the manipulation of basic mathematical constructs, the paradigmatic 'abstract idea'")" recited at page 14 of the "Guidelines" are examples of the abstract.

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Applicants' process does not convert or process just any data but is limited to useful concrete and non-abstract gene expression profiles in a data base of such profiles. Applicants' process is but one application of many possible applications of the mathematical steps involved in obtaining the useful result.

At page 17 of the "Guidelines we see:

While abstract ideas, natural phenomena, and laws of nature are not eligible for patenting, methods and products employing abstract ideas, natural phenomena, and laws of nature to perform a real-world function may well be. In evaluating whether a claim meets the requirements of section 101, the claim must be considered as a whole to determine whether it is for a particular application of an abstract idea, natural phenomenon, or law of nature, rather than for the abstract idea, natural phenomenon, or law of nature itself.

As is clear from the specification and the claim limitations, Applicants' process is limited to a particular application and is not an abstract idea, natural phenomenon or a law of nature.

For example claim 1 recites:

"processing a number of gene expression profiles with a similar sequences algorithm that is a time and intensity invariant correlation function to obtain a data set of gene expression profile pairs and a match fraction for each gene expression profile pair;

listing gene expression profile pairs in clusters by their match fractions;

removing a first gene expression profile from a cluster when another cluster has another gene expression profile with a higher match fraction with the first gene expression profile, unless the another gene expression profile requires a larger number of subsequences to achieve similarity with the first gene expression profile;

repeating the removing step until all gene expression profiles are listed in only one cluster;"

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The result is that all of the processed gene expression profiles are each listed in only one cluster. This result of applicants' claims is a very useful, repeatable and non-abstract result which is recognized by those skilled in the medical and computer arts to be of great value and useful, non-abstract and concrete finding of similar gene expression profiles.

Webster's Seventh New Collegiate Dictionary defines tangible as:

1a) capable of being perceived, especially by the sense of touch: PALPABLE;

1b) substantially real: MATERIAL

2) capable of being precisely realized by the mind

3) capable of being appraised at an actual or approximate value (assets)

The definition 2) appears to be the most appropriate to this issue. It is applicants position, supported by the "Guidelines", that it is not a requirement that applicants claims be limited to a result in certain forms of output such as to a user, in order for a result to be capable of being precisely realized by the mind. Applicants' invention is not in the output apparatus or output process but is in the limited steps recited above in example claim 1. To require applicants to limit their claims to recited outputs is to require unnecessary limitations that can be easily avoided by potential infringers.

In the interest of furthering the prosecution of this application, applicants have added "to a user" to claims 1 - 6 and 20 without admitting that such limitation is required for novelty, by statute, by court decision or under the "Guidelines".

Claims 1, 2, 4, 6, 12, 14, 16 and 20 continue to be rejected under 35 U.S.C.112 second paragraph on the ground that the specification does not provide a meaning for the word

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"subsequences". The Examiner finds Figures 4 and 6 and paragraphs 48 - 50 to be unclear.

The specification at paragraph 15 recites:

[0015] According to the instant invention, two temporal sequences are similar and can be placed in the same cluster if they have enough non-overlapping time-ordered pairs of sub-sequences that are similar.

Paragraph 50 recites:

[0050] FIG. 4 exemplifies noise resistance and partial similarity. When one looks at *gene 4* and *gene 3*, it is clear that most likely, the value of 10 for *gene 3* at $t=3$ is an outlier. This data point could have occurred, either from manual error or instrumentation error. The Agrawal Fast Similarity Search algorithm will minimize this artifact data point by its design, and identify two matching areas. The profile from $t=1$ to $t=2$ is identified as one subsequence and the profile from $t=4$ to $t=6$ as another subsequence. Since it has minimized this "outlier or noise", it is able to identify these two genes as similar in function.

Applicants believe that it is clear to those skilled in the art that the genes 3 and 4 in Figure 4 are temporal sequences from time 1 through time 6 and that each sequence includes subsequences from time 1 to time 2 and from time 4 to time 6.

In the event that the Examiner continues to assert this 112 rejection, it will be helpful to applicants in deciding whether to appeal or file a request for continued examination, if the Examiner would identify more specifically why the Examiner finds the language of the specification and claims to be unclear. What alternative meanings could possibly be understood from the specification other than that a subsequence is part of a temporal sequence as described?

PRIOR ART

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Applicants note that their claims have not been rejected on prior art yet have been restricted on the ground that there were two groups of claims that required two fields of search. It is not apparent whether relevant **prior art patents** were considered by the Examiner while examining this application.

It is believed that the "Guidelines" on page 10 are helpful in determining both the novelty of applicants' method and the **usefulness and non-abstract nature** of the result of applicants' claimed method.

As evidenced by the references which applicants have attempted to incorporate by reference, but have acquiesced to the Examiners requirement to cancel, in addition to applicants teachings in the background art, users in the medical profession find great value and usefulness in methods for finding similar gene expression profiles that are tangible and concrete. See for example 6,406,853 abstract and claims 25, 26 and 6,436,642 column 26 beginning at line 15.

It is believed that if the rejections under 35 U.S.C. 101 put forth in this application were appropriate, many of the relevant prior art patents in the appropriate fields of search would be found to be invalid. Since they were issued under the guidance of current statutory law and court cases, it must be that the rejections in this application are based upon excessively narrow and untenable interpretation of the current law.

A problem existing in the prior art for finding such similar gene expression profiles is that current methods of discovering functional similarity in genes use only the intensity of expression. However, the intensity of gene expression can vary

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with time and follows a specific pattern. For example, progression through the eukaryotic cell cycle is known to be both regulated and accompanied by characteristic periodic fluctuations in the expression levels of numerous genes. Thus a better method was needed to find gene expression profiles in a data base of profiles that were indeed similar and applicants have invented such a method which they claim in clear concise and unambiguous language that has not been found to be anticipated or made obvious by any cited prior art teaching of which there are significant amounts extant.

It is well known in the art as exemplified throughout the teachings relevant prior art patents that users in the medical profession receive output from computer input/output devices such as applicants teach in their preferred embodiment. See for example 6,406,853 abstract and claims 25, 26 and 6,436,642 column 26 beginning at line 15. It is furthermore clear from such prior art that applicants addition of the step of providing such output to satisfy the Examiner's narrow reading of the claims is not new matter but is supported in their specification by teachings allowing anyone skilled at a rudimentary level of using a computer to make and use the invention and understand the scope of the claims.

Accordingly it is believed that the claims are clear, statutory and definite and are drawn to a novel and unobvious method and program product for clustering gene expression profiles which result is concrete, tangible and directly useful in drug selection and disease diagnosis.

Applicants sincerely request that the Examiner reconsider all of the rejections of this application and find it to be allowable.

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If it will be helpful to the Examiner, applicants' attorney will be available after July 5th to answer any questions or respond to any suggestions that the Examiner may have to dispose of this application.

Respectfully submitted,

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